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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,048	07/28/2003	Stuart Brown	26859-002UTIL	7394

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EXAMINER	
STOUT, MICHAEL C	
ART UNIT	PAPER NUMBER
3736	

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09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,048	BROWN, STUART	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-30* is/are pending in the application.

4a) Of the above claim(s) *11,13-15,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10, 12, 16-23 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/629,048 filed on 07/28/2003 and is a first action based on the merits of the application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 29 and 30 recited the limitation of greater than about 50 of said isolated chambers, it is unclear in light of the applicants specification what is encompassed by about 50. On page 5, Lines 13-18 the Applicant teaches the device comprising 2, 5, 10, 20, 50 and upto hundreds, it is unclear whether the 2, 5, 10, or 20 can be considered about 50, and therefore the scope of the claim cannot be determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 10, 12, 16-19, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosse et al. (WO 00/44285), or alternatively unpatentable over Mosse et al. in view of Krulevitch et al. (US 5,928,161).

Mosse discloses a method of extracting multipletissue samples from a subject, comprising: inserting into the subject an instrument (figure 1) comprising a plurality of controllable tissue sampling devices (15, 21), each of said devices being located in a different position in an array along a longitudinal axis of a housing (figures 2a-2b), each of said sampling devices comprising an isolated chamber (15); contacting a sampling device with a deployment signal (page 6, lines 20-22), said signal being a hydraulic signal (page 8, lines 6-8), said signal causing an opening (page 7, lines 4-6) of said chamber; removing (page 6, line 24) a tissue sample from an anatomical location adjacent to said chamber; and sealing (page 7, line 1) said chamber. The housing comprises an interior lumen containing a deployment control element (32). The chambers do not communicate the tissue sample to the interior lumen. The housing is solid and the deployment control device is embedded in said housing. The tissue sampling devices are fixed in position along an outside diameter and are radially disposed about an outer diameter and longitudinally disposed along the length of the instrument. The chambers are vacuum sampling chambers (page 6, lines 15-17). The sampling device are deployed simultaneously in time. Mosse does not expressly disclose the device wherein the volume of said isolated chamber is less than 1.2 cubic millimeters that the volume of the isolated chamber ranges from 0.001 to 1 cubic millimeter, selected from the group of 0.005, 0.01, 0.05, 0.1, 0.5, 0.75. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the volume of the chambers less than 1.2 cubic

millimeters and between 0.001 and 1 cubic millimeters or selected from the group of 0.005, 0.01, 0.05, 0.1, 0.5, 0.75 because Applicant has not disclosed that the range of volumes and specific volumes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a different chamber volume because the instrument would still successfully obtain biopsy samples. Therefore, it would have been an obvious matter of design choice to modify Mosse to obtain the invention as specified in claims 1, 16, 17, 27 and 28.

Nevertheless, Krulevitch teaches a biopsy device for collecting tissue samples for use in Polymerase Chain Reaction analysis discloses a tissue receiving chamber 44 for determining the size of the tissue to be sectioned, wherein the size of the recess may have a with of 1.0mm and a length of 0.5mm and a depth determined by the desired thickness of the tissue sample to be taken 2 to 500 micrometers, see Abstract Column 4, line 50 through Column 5, Line 13. Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention taught by Noose to have a chamber volume of less than 1.2 cubic millimeters and between 0.001 and 1 cubic millimeters or selected from the group of 0.005, 0.01, 0.05, 0.1, 0.5, 0.75 depending on the desired thickness of the tissue sample to be taken. Krulevitch teaches the variation of ranges depending on desired sample size and the applicant does not Applicant has not disclosed that the range of volumes and specific volumes provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.

Regarding claims 29 and 30, Mosse further teaches the invention wherein the device comprises 16 recesses (about 50, in light of page 5, Lines 13-18 of the Applicants specification) and wherein the number of recess may be increase, see Page 3, Line 20 through page 4, Line 1. Mosse fails to explicitly disclose the invention wherein said instrument comprises greater than 50 of said isolated chamber. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make invention comprise greater than about 50 of said isolated chamber because Applicant has not disclosed that the range of volumes and specific volumes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with varying numbers of chambers with predictable results, as evidenced by Mosse Page 3, Lines 20-25 and the Applicants specification page 5, Lines 13-19.

Claims 7, 20-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosse et al. (WO 00/44285), (or Moose/Krulevitch) in view of Sorensen et al. (US 5,320,627).

In regards to claim 7, Mosse discloses a heat conductive cover element (13) but does not expressly disclose a heating element. In regards to claim 20, Mosse does not expressly disclose heating the plurality of sampling devices, wherein the heating causes actuation of a mechanical portion, such that the mechanical portion collects a sample

and retains the sample. In regards to claim 21, Mosse does not expressly disclose passing an electrical current through a portion of the extracting device. In regards to claim 22, a differential pressure is applied to a local chamber to such in the sample. In regards to claim 23, the samples can be ejected by pressurizing the chamber (page 7, lines 13-14). In regards to claim 26, the method further includes imaging a location of the sample fiberoptically (page 6, line 12).

Sorensen teaches a heating element that uses electrical current for causing actuation of a shape memory alloy mechanical portion to collect and retain a biopsy sample (column 10, lines 31-53). Sorensen teaches these components as an alternative to mechanical actuation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a heating element for causing actuation of a mechanical portion to collect and retain a biopsy sample as taught by Sorensen in place of the mechanical actuation of Mosse in order to achieve the predictable result of actuating a biopsy mechanism to obtain biopsy sample.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

Applicant's arguments filed 4/07/2008 with respect to claim 16 have been fully considered but they are not persuasive. The Applicant argues that the change in size of the chambers is not an obvious matter of design choice because the method provides the distinct advantages of "For example, the analysis and examination or smaller tissue and/or fluid samples reduce the amount of tissue required per analytical procedure. Analytic methods, e.g., Polymerase Chain Reaction (PCR), are used to obtain diagnostic information. The instrumentation and sampling methods described herein permit the replication of genetic data from very small samples, eliminating the need for large tissue samples.' The Examiner Disagrees. As supported in the specification the Applicant has not disclosed that this specific range of volumes provides an advantage, is used for a particular purpose, or solves a stated problem, it is PCR not the chamber volume that provides the analysis of small sample sizes. The samples collected from the device taught by Moose are capable of being used in analytical methods such as Polymerase Chain Reaction (PCR). One of ordinary skill in the art, furthermore, would

have expected Applicant's invention to perform equally well with a different chamber volume because the instrument would still successfully obtain biopsy samples.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736